QAM 12070: GRADED APPROACH PROCEDURE

Revision History

Author	Description of Change	Revision Date
Tom DiGrazia TJ Sarlina	• Added definitions for "Failure mode" and "Effects analysis" • Added section **5.5.1**, Failure Mode and Effects Analysis (FMEA) • Added general requirements for procedures • Added general requirements for Quality Control plans	February 2021
Jemila Adetunji	• Updated roles and responsibilities, and addition of 3.4 Fermilab Risk Officers; • Clarification of definitions, program description, and procedure sections; • Removal of approval requirement; • Updates to references section.	January 2018
Kathy Vuletich	Initial release of QAM chapter replaces OQBP Graded Approach Procedure 1002.1000 rev. 000.1 B10.	December 2013

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1.0 INTRODUCTION

The purpose of the graded approach is to guide the selection of the level of controls to be applied to activities which pose the greatest risk or significant negative impact on operations or laboratory reputation. This focuses management attention on activities which require the most control and oversight and reduces costs by minimizing the application of controls in areas of low risk. Applying the graded approach to select the appropriate level of control includes developing procedures where necessary to ensure tasks are carried out properly and with all appropriate precautions.

This chapter is applicable to all activities carried out at the Batavia site as well as FRA leased spaces.

2.0 DEFINITIONS

Activities – This encompasses a wide range of work performed to meet the lab's mission, including but not limited to operations work, basic and applied research, software development, procurement, design, construction, modification, and decommissioning,

Effects analysis– The study of the consequences of a failure mode being realized.

Failure mode – The way in which something may fail due to an error or defect.

Grading – Selecting the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

Risk – A fundamental consideration in determining the extent to which controls should be applied at the facility level.

3.0 RESPONSIBILITIES

3.1 Division/Section Heads and Project Managers (D/S/P)

D/S/P's are responsible for applying the graded approach to activities under their control. They provide the necessary resources to implement and maintain the graded approach process.

3.2 All Employees and Users

Process owners, managers, supervisors, scientists, and engineers are responsible for ensuring that the graded approach procedure is appropriately applied to their activities.

3.3 Quality Management System Owner

Ensures that this process is applied accordingly, and this document maintained.

3.4 Fermilab Risk Officers

All Fermilab Risk Officers are responsible for ensuring that the graded approach procedure is applied to activities pertaining to the identification and management of risks in their areas.

4.0 PROGRAM DESCRIPTION

The graded approach process is part of Fermilab's Quality Assurance Program. The Program is based on the principle that the people best suited to identify, understand, and assess risks are the people who

plan and perform the work. This chapter describes an incremental process which guides the user in determining the level of controls suitable for managing the risks posed by an activity.

The grading process can be broken down into three steps:
1. Identify the hazards, consequences, and probability of failures for the work being performed.
2. specify the requirements and controls to be applied. The third step is to determine the depth, extent, and degree of rigor necessary in the application of the requirements and controls.
3. Communicate and implement the appropriate requirements and controls. The necessary degree of rigor should be applied by means of documented work processes (procedures, instructions, specifications, and controls).

The application of this process depends on the mission of the organization performing the evaluation and is intended to be implemented at all levels. Each D/S/P has the freedom to tailor a grading scale that will fit their specific needs. Factors such as cost, schedule, environment, health, safety, quality, mission, public perception, and security shall be considered when grading quality requirements.

The graded approach process goals are to:
- Identify activities which present significant operational risks
- Determine the risk levels
- Determine the necessary controls and requirements to be applied
- Determine the depth, extent, and degree of rigor in the application of requirements
- Document and approve the determination

5.0 PROCEDURES

When using a graded approach, it should be noted that some activities identified are unique to D/S/P's and shall be evaluated by the responsible D/S/P, while other programmatic activities will cut across organizational lines. It is the responsibility of the process owner, in this case, to include the head (or designated representative) of each affected D/S/P in the review and selection of controls applied in cross-functional situations.

5.1 Identify Activity & Risk

Identify activities presenting a significant risk if proper controls are not in place. Examples include:
- Processes identified as critical
- Control failures that result in program downtime or a delay to the laboratory schedule
- Single point failures of equipment that may jeopardize project budgets or schedules
- Control failures that may compromise data quality or result in complete or partial loss of data
- Activities that can cause injuries, environmental hazards, liabilities, or risks greater than those generally accepted in a research environment
- Occurrences that could cause a significant reduction in the public trust or scientific reputation
- Routine activities that must be performed by multiple individuals. Examples include preventative maintenance tasks, calibration of experimental apparatus, Lockout/Tagout operations, etc.

Procedures should be developed for activities that fall into any of the categories listed above in the bulleted list. If a standard procedure format does not already exist, a general one is provided in Appendix B of this chapter.

5.2 Define Steps of Activity

Identify the activities that present a significant risk and all the steps involved in those activities that have been chosen. Ensure these activities are documented appropriately in accordance with Fermilab's Document Management & Control Policy. When understanding the chosen activities:

- Consider goals of the activities, inputs, outputs, operating constraints, and interactions.
- Consider utilizing subject matter experts.
- Consult with individuals from other organizations if an activity involves that organization.

5.3 Evaluate Current Risk

Evaluate the current state of the identified activity and controls that are already in place. Determine the known risks associated with each activity, adequacy and effectiveness of controls for each risk, and identify any remaining risks. Factors such as cost, schedule, environment, health, safety, quality, mission, public perception, and security shall be considered when evaluating risks.

5.4 Assign Graded Risk Level

Risk Level for Activities

Assign a graded risk level to each activity based on the potential impact for the risks identified. Activities rated as higher risk/high impact will require a higher degree of control and risk management as opposed to activities rated as low risk/low impact. As stated above, factors such as cost, schedule, environment, health, quality, safety, mission, public perception, and security shall be considered when grading risk levels. Refer to QAM Chapter 12030 – Fermilab Quality Tool Suite Procedures and Risk Assignment.

Risk Level for Software Applications

In accordance to the QAM Chapter 12090, Software Quality Assurance Grading and Inventory Procedure, each D/S/P shall determine their own quality grade levels that best fit their needs for software applications they manage. For example, the Software Quality Assurance Program identifies 3 quality grade levels to grade software applications. Software is graded high, moderate, or low depending on the worst consequence if controls fail.

- High Risk – Consequences such as injury or death, environmental hazards, release of DOE sensitive information could occur.
- Moderate Risk – Consequences such as program downtime, or minor disruptions in laboratory operations could occur.
- Low Risk – Consequences such as reduction in data quality could occur.

Risk Level for Projects

Projects also identify risks associated with their Work Breakdown Structure and develop appropriate risk registers to apply to their tasks. In both cases, applications or operations graded as high risk would require more controls than those graded as low risk.

5.5 Select Risk Management Strategies & Identify Additional Controls

Select the risk management strategy that best fits the activity being evaluated and the grade level assigned to the activity.

Fermilab has several established methods to assist in determining appropriate controls and risk management strategies to implement. They include, but are not limited to, the following:

- Project risk plans for scientific research project teams – tools used include Primavera Risk Analysis and Risk Registers
- Risk plans used for ITIL (Information Technology Infrastructure Library) implementation and other Computing Sector projects
- Fermilab Engineering Manual – tools used include Risk Assessment Spreadsheet
- QAM Chapter 12030 used for risk management for ESH&Q – tools used include iTrack
- QAM Chapter 12003 – Software Quality Assurance Program
- FESHM Chapter 2060 – Work planning and hazard analysis
- Operational Readiness Clearances and Accelerator Readiness Reviews
- Failure Mode and Effects Analysis (FMEA)

Determine where controls are missing. Identify the controls that are necessary to close the gaps, and mitigate risk based on the quality level and risk management strategy selected. For example, the Software Quality Assurance Program ensures proper controls are put in place depending on the quality grade level assigned to software applications. The output of this step shall be that adequate controls are chosen, and risk management strategies identified to mitigate the risk of impact on quality regardless of the method or tools employed.

5.5.1. Failure Mode and Effects Analysis (FMEA)

A risk analysis tool which can be used to determine where controls are missing is Failure Mode and Effects Analysis (FMEA). FMEA is a step by step approach for identifying and analyzing all possible points of failure within a design or process. Appendix A of this QAM chapter provides further guidance on completing a FMEA along with a template. For the FMEA tool required for Cryogenic System Reviews, see FESHM 5032.

5.6 Documentation

The process for documenting the results from risk analysis should be defined by the Division, Section, Project, or Functional Area. Lessons learned (QAM 12010) should be shared with the laboratory, when appropriate.

Results of risk analysis efforts can help individuals identify the level and types of quality control tests, checks, and inspections needed for a particular process or design. These quality control activities identified can be documented in a Quality Control (QC) Plan. Appendix C of this QAM chapter provides further guidance on QC Plans along with a template.

6.0 REFERENCES

Fermilab Quality Assurance Program
QAM 12003: Fermilab Software Quality Assurance Program
QAM 12010: Fermilab Lessons Learned Program
QAM 12030:Fermilab Quality Tool Suite Procedures and Risk Assignment
QAM 12090: Software Quality Assurance Grading and Inventory Procedure
FESHM Chapter 2060 - Work planning and hazard analysis
FESHM 5032 – Cryogenic System Review

7.0 Appendix A - Risk Analysis Tools

- Failure Mode and Effects Analysis (FMEA)
  - Definition
    - FMEA is a tool that facilitates a step-by-step approach for identifying all potential failures within a design, process, or that may be imposed by external factors. The tool prioritizes the failures identified by taking into consideration how critical the effects of a failure are, how often the failure may occur, and how easily the failure can be detected. The purpose of the FMEA process is to take actions to eliminate or reduce the likelihood and/or impact of failures with a focus on the high priority failures identified. Ideally, the FMEA process starts at the conceptual design phase and continues throughout the lifecycle of the design process.
  - When to use
    - When a process or device is being designed or re-designed
    - Periodically throughout the lifecycle of a design effort
    - When a failure is realized
  - FMEA Template
    - A template for FMEA is provided here: DIRECTORATE-doc-551
  - Procedure
    - **Identify the scope**
      - The device or process being analyzed
    - **Assemble a team**
      - A cross-functional group of individuals with diverse knowledge of the device or process being designed
    - **Populate the identifying information (header of template)**
      - Process/Design - Name of the process or design
      - Author – Name of the individual populating the FMEA
      - Core Team – Members of the team providing input to the FMEA
    - **Populate each column of the FMEA template**
      - **Process Step, Item/Function, or External Condition -** Identify the functions of the scope
        - For process FMEA, identify each of the steps in the process (process step). These should be listed in the order in which the steps are performed, i.e. Chronological.
        - For design FMEA, identify the item being analyzed and it's function (Item/Function). This can be a design feature, a component, subsystem, or complete system. The function describes what the item does. There may be multiple functions for a single item.
        - For external condition FMEA, identify each external factor that can have a negative impact on the design (external condition). Common external conditions include power outages, transportation delays, etc.

- **Potential Failure Mode** – Identify all the ways a failure can happen for each function identified
- **Potential Effect(s) of Failure** – For each failure, identify all the consequences
- **Severity** – How serious the effect is.
    - The template provides guidance in the form of a Severity Matrix. This matrix is defined in QAM 12030 Technical Appendix - Table 1.
    - Select from the drop-down the severity level determined
    - If a failure mode has more than one effect, consider the effect with the highest severity.
- **Potential Cause(s)/Mechanism(s) of Failure –** For each failure, identify all the potential root causes.
    - QAM 12050 - Root Cause Analysis provides guidance on determining root cause by describing the activities required to properly perform a root cause analysis
- **Probability –** The probability of failure occurring throughout the lifecycle of the scope.
    - The template provides guidance in the form of a Probability Matrix. This matrix is defined in QAM 12030TA Table 2
    - Select from the drop-down the probability level determined.
- **Current Controls (Prevention)** – For each root cause identify the current controls in place to prevent or reduce the likelihood of the failure mode from occurring.
    - Describe how the failure mode is prevented based on the current or planned actions
    - The controls identified here should be used as input in determining the Probability level
- **Current Controls (Detection)** – For each root cause, identify the current controls in place to identify a failure mode that has been realized.
    - Describe how the failure mode or the cause is detected based on the current or planned actions.
    - The controls identified here should be used as input in determining the Detection level.
- **Detection –** The probability that, if realized, the failure mode will be detected.
    - The FMEA template provides guidance in the form of a Detection Matrix table. A table is provided for each FMEA type (Process, Design, External)
    - Select from the drop-down the detection level determined.
- **Risk –** The risk number takes into consideration the severity, probability, and detection level and provides a method for ranking potential failures in the order they should be addressed.
    - Automatically determined based on severity, probability

- Columns to the far right are optional and are used to help reduce the risk of failure modes identified.
    - These can be used in a proactive manner to help reduce the risk number of high-risk items.
    - These can be used in a reactive manner, identifying actions to address failure modes that have been realized.

    - **Recommended Action(s)** – Actions identified to help lower the risk.
        - Consider actions that improve the design or process to lower the severity or occurrence.
        - Consider actions that provide additional controls to increase the likelihood of detecting a failure mode that is realized.
    - **Responsibility –** Identify the individual(s) responsible for completing the recommended action(s) identified.
    - **Target Date –** Date that the identified action(s) can be reasonably achieved.
    - **Actions Taken –** Notes on what was completed to address the actions identified.
    - **Severity, Probability, Detection, and Risk –** Select the new severity, probably, and detection level after having completed the action(s) identified.

8.0 Appendix B - Suggested Procedure Format

Procedures should contain the following information in a header:

- D/S/P and/or group that owns the procedure
- Procedure name and number
- Name of Author
- Name of Reviewer/Approver
- Approval date
- Revision History

Procedures should contain the following information in the body:

- Purpose
- Materials and/or Prerequisites Required
- Safety equipment/PPE
- References (if applicable)
- Definitions (if applicable)
- Detailed procedure steps
- Documentation requirements

Here is a link to a general procedure format that can be adapted for use by any group: DIRECTORATE-doc-526

9.0 Appendix C - Quality Control Plan

A general quality control plan template is provided and can be found here: DIRECTORATE-doc-554. Multiple sections are provided in the template and all should be considered when developing the plan. Provided below is guidance on the intent of each section and what it should contain.

- Scope of Quality Control (QC) Plan
  - This section defines the scope of work that the QC plan will cover. Describe the design and/or process that is being developed.
- QC Test and Measurements
  - Brainstorm all of the QC tests and measurements that should be performed on the design/process. Think about what needs to be checked to provide a confidence level that the design/process will meet the requirements defined. When developing procedures/travelers, this section can be referred to and used to verify all tests/measurements identified are being captured.
- Requirements Traceability
  - This section provides a method of ensuring all of the requirements defined for the design/process are being verified. List out all of the requirements and trace how each will be verified as being met. Consider the inspections and measurements listed in the "QC Test and Measurements" section. Simulations, demonstrations, and analysis efforts should also be considered.
- Travelers, Procedures, and Checklists
  - This section provides a list the travelers, procedures, and checklists that need to be developed to perform the QC work. Brainstorm and list out all of the travelers, procedures, and checklists that will be needed. As these documents are developed, update the QC plan with a reference to each.
- Acceptance Tests & Criteria
  - When receiving deliverables from an external source, acceptance testing should be performed to ensure the deliverable meets requirements and expectations. External sources may include vendors, subcontractors, and partner labs/institutions. When delivered from other areas within Fermilab, this may also be considered an external source. Similar to the "QC Test and Measurements" section, brainstorm and list out the QC tests and measurements which will be performed upon receipt of the deliverable.
- In-process Monitoring and Measurement Activities
  - This section is to be used when a vendor is performing fabrication/assembly efforts that require in-process oversight. Describe the activities at the vendor which will require hold, witness, notification, and/or review points. Manufacturing Inspection Plans (MIPs) can be developed and referenced here.
- Verification Plans: Methods & Activities
  - Describe how all of the QC activities planned will be verified as being completed. Consider all of the travelers, procedures, and checklists identified and planned to be performed. The methods/activities described here should prevent any of these from being missed.
- Deliverable Documentation and Records

  - Describe all of the documents and records which will be generated and delivered along with the device or service being provided. Consider completed travelers, certifications, checklists, etc.
- Associated Equipment
  - List out all of the equipment required to carry out the QC activities described in this plan.
- Calibration Plans
  - Describe the calibration requirements for the associated equipment identified.
- Traceability Requirements
  - Describe the requirements for tracing delivered devices. Consider assemblies/subassemblies/individual components and what will require unique identification (i.e. serialization) for traceability purposes.
- Training and Qualification
  - This section should describe the training and qualifications required for performing the QC activities described in this plan. Also consider the training/qualifications required for performing the fabrication and assembly efforts.
- Planned Partner and Vendor Communication & Visits
  - When applicable, describe the communication and visits planned with the vendor/partner.
- Control of Nonconformances
  - Define the process that will be used when nonconformances are identified. Describe how nonconformances will be documented, dispositioned, resolved, approved, and shared.
- Transportation/Shipping
  - Describe any special transportation/shipping efforts that will be required or if standard shipping methods/practices will be used.
- Risk Analysis Documentation
  - List out and reference all of the documentation that came out of risk analysis efforts such as a Risk Assessment or Failure Modes and Effects Analysis spreadsheet.